



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,588	01/23/2002	Jennifer L. Pavlovic	19369/116/101	4695

9561 7590 01/30/2004

POPOVICH, WILES & O'CONNELL, PA
650 THIRD AVENUE SOUTH
SUITE 600
MINNEAPOLIS, MN 55402

EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/30/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

Office Action Summary

Application No.

10/056,588

Applicant(s)

PAVLOVIC, JENNIFER L.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 14, 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 4, 14, 16, and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 15, 17-23 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 and 6. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claims 1-3, 5-13, 15, 17-23, and 27-31 in Paper No. 11 is acknowledged.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show [label] component 70, as described in the specification. Figure 5d should have number 70 labeled. Figures 8 and 9 should have fiber matrix 14 labeled [see specification page 24, 2nd and 3rd full paragraphs]. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 5, 6, 8, 9, 13, 15, 19, 20, 27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,610,077 to Hancock et al. Regarding Claims 1, 19, and 20 Hancock discloses an emboli filter (70), for catching debris in a blood vessel. With reference to *Figure 4A*, Hancock discloses two flexible wires (72 and 74) oriented to define a perimeter. These wires are quite thin and can therefore be flexed with minimal force applied. These wires form a *frame*. Hancock also discloses a fiber matrix (76) [Column 7, lines 52-54] secured to the frame. The fibers are spun (wrapped) around the two wires (72 and 74) criss-cross to form many spaces, interstices and pores between them. The filter (70) is carried on a guide wire (28) [Column 7, lines 44-47]. The filter is collapsible and expandable to engage the walls of the lumen [Column 8, lines 1-13].
4. Regarding Claims 5, 6, 8, and 9, Hancock discloses a self-expanding filter. The loops of wire (72 and 74) self-expand because they are made out of nitinol [Column 8, lines 5-11].
5. Regarding Claims 15 and 27, the fibers (76) are randomly bent and twisted, as they are strewn from wire (72) to wire (74) [embodiment shown in Figure 4A]. Therefore, the pores between the fibers (76) will also be randomly, or irregularly, shaped.
6. Regarding Claim 13, Hancock discloses a single strand, which forms the fiber of the matrix [Column 7, lines 52-54].

7. Regarding Claim 30, Hancock's wire (24) is said to have a diameter of 0.003 inches, and is the same component as wire (70) [Column 7, lines 3-7; compare Figure 1B with Figure 4A].

8. Claims 1-3, 5-7, 10-12, 17-23, 28, 29, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,540,768 to Diaz et al. Regarding Claims 1, 19, and 20, Diaz discloses an emboli trap with a wire frame. The wire frame has a plurality of wires (S), which define a circular perimeter [Fig. 24]. Each segment (S) can be considered a separated wire segment. Wires (50/51) in Figure 3 also define a circular perimeter. Any cut taken from conical filter shown in Figures 3-5b will be a circle, and wire (50) will intersect that circle.

Diaz discloses a fiber matrix ("filter membrane 20") secured to the wire frame [Column 5, lines 22-28]. Diaz's fiber matrix allows blood to pass, but not particulate matter [Column 5, lines 22-28]. Figure 5A shows the filter in its collapsed configuration, and Figure 5B shows it in its expanded configuration. Diaz's filter is carried by a guide wire (10) [Column 5, lines 3-10].

Regarding the method of manufacture of the filter ["plurality of wires on which said fibers are spun to form a matrix"], Diaz's filter is capable of being manufactured in this way.

9. Regarding Claims 2 and 3, Diaz's filter is collapsible and does not need a catheter/constraining wall in order to collapse—it has its own mechanism for

collapsing as seen in the progression from Figure 2 to Figure 1 and described in Column 5, lines 3-10.

10. Regarding Claims 5, 6, and 29, Diaz's wire frame (50/51) is metallic [Column 5, lines 19-21]. They can also be made of nitinol [Column 5, lines 43-47]. Wires (S) are also assumed to be metallic, because all of the other structural support elements (50/51) are disclosed as being made out of stainless steel or nitinol.
11. Regarding Claims 7 and 23, Diaz's fiber matrix (20) and integral wire frame (50/51) form boundaries defining many pores. The mesh is connected to the wire frame (50/51) and being that the mesh has many pores, some of these pores will abut the frame, forming pores together with the wire.
12. Regarding Claims 10, 11, 12, and 31, Diaz's fibers (20) are capable of being formed by electrospinning. The fibers (20) are also capable of being applied individually. They are also capable of being applied in a flowable state, as they are made out of a metal [Column 5, lines 36-40], and have a liquid form when heated. However, *no additional structure is claimed by claiming a method of manufacturing the fibers, or a method of applying them to the frame (50/51).*
13. Regarding Claim 17, Diaz discloses pores, which are 50-150 microns in size [Column 5, lines 27-30].
14. Regarding Claim 18, Diaz discloses a filter material having laser-drilled holes with an open area of 10-50 percent. This open area corresponds to a hole size of 50-300 microns [Column 8, lines 36-51]. Therefore his mesh, which also has a hole size

Art Unit: 3731

of 50-300 microns [Column 5, lines 27-30] will also have an open area of between 10-50 percent.

15. Regarding Claims 21 and 22, Diaz discloses a flexible catheter [sheath] (180) that holds the frame in its collapsed position [see Fig. 14; Column 7, lines 61-65]. Nylon is a flexible material, and the catheter must navigate through the turns in the blood vessel. The catheter (180) is carried by guide wire (164) and holds the flexible frame of the emboli trap inside of it [see Fig. 15].
16. Regarding Claim 28, Diaz's frame is windsock shaped [Figures 5B, 7, 9, 11, 14].

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,558,405 B1 to McInnes

U.S. Patent No. 6,458,502 B2 to Don Michael et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

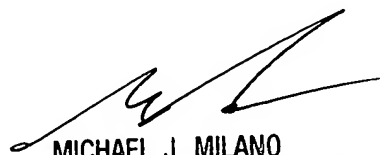
Art Unit: 3731

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP

BCP

January 23, 2004



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700